

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0161]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Information From United States Processors That Export to the European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the **Federal Register**]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Information From U.S. Processors That Export to the European Community—(OMB Control Number 0910–0320)—Extension

The European Community (EC) is a group of 15 European countries (with 10 additional countries joining on May 1, 2004), that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intraEC trade has been extended to trade with nonEC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

- (1) Business name and address;
- (2) Name and telephone number of person designated as business contact;

(3) Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;

(4) Name and address of manufacturing plants for each product;

(5) Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection; and

(6) Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of 18 U.S.C. 1001. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

In the **Federal Register** of April 16, 2004 (69 FR 20630), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Product	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Shell eggs	10	1	10	0.25	3
Dairy	100	1	100	0.25	25
Game meat and meat products	5	1	5	0.25	1
Animal casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					32

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (DISCLOSURE)¹

Product	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
Trade association	15	1	15	8	120
State	50	1	50	8	400
Total					520

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

It is estimated that the annual reporting burden would be no more than 32 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. The number of

respondents is a rough estimate based on volume of exports and responses received to date. No record retention is required. Therefore, the proposed annual burden for this information collection is 32 hours.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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